UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Church & Dwight Co. Inc.,

Plaintiff,

–v–

SPD Swiss Precision Diagnostics, GmbH,

Defendant.

14-CV-585 (AJN)

MEMORANDUM AND ORDER

ALISON J. NATHAN, District Judge:

The present motion *in limine* asks the Court to decide whether the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360c, bars certain false advertising claims brought under the Lanham Act, 15 U.S.C. § 1125(a). More accurately, the question is whether the FDCA bars Lanham Act false advertising claims relating to medical devices if the Food and Drug Administration ("FDA") pre-approved the medical device's labeling. The Court answered this question in the negative at the motion to dismiss stage, but it indicated that a different result might be reached on a more fully developed record and after the Supreme Court's anticipated decision in *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014). *See Church & Dwight Co. Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14 Civ. 00585 (AJN), 2014 U.S. Dist. LEXIS 76752, at *21-43 (S.D.N.Y. June 3, 2014) ("*Church & Dwight I*"). Shortly thereafter, the Supreme Court rendered a decision in *POM Wonderful*, which only strengthens the Court's earlier analysis on this point. Therefore, Defendant Swiss Precision Diagnostics, GmbH ("SPD")'s motion *in limine* to bar Plaintiff Church & Dwight Co. Inc. ("C&D")'s Lanham Act claim is DENIED.

I. LEGAL STANDARD

Generally, "'[t]he purpose of a motion in limine is to allow the trial court to rule in advance of trial on the admissibility and relevance of certain forecasted evidence.'" *Great Earth*

Int'l Franchising Corp. v. Milks Dev., 311 F. Supp. 2d 419, 424 (S.D.N.Y. 2004) (quoting *United States v. Paredes*, 176 F. Supp. 2d 192, 193 (S.D.N.Y. 2001)). And "[w]hile 'dismissing claims is not the prototypical purpose of a motion in limine,' such motions have sometimes been addressed on the merits and have sometimes 'been construed as or converted into motions to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure or motions for summary judgment under Rule 56.'" *Id.* (quoting *Fournier v. McCann Erickson*, 242 F. Supp. 2d 318, 334-335 (S.D.N.Y. 2003)).

As noted, the issue raised in this motion *in limine* was first raised at the motion to dismiss stage, which coincided with a motion for a preliminary injunction that the Court consolidated with an expedited bench trial on liability. Although the motion to dismiss was denied, the Court informed the parties that it was prepared to reconsider its ruling on a more fully developed record. At a subsequent conference with the parties, SPD requested permission to raise the FDCA preclusion issue as a pre-trial motion and contended that briefing could be done on the basis of the record as it then existed. Status Conf. Tr. 12:10-19, Aug. 12, 2014. The Court made clear that it discouraged summary judgment motion practice in bench trials and, because it wished to avoid a "duplication of effort, coupled with the fact that [the Court was] not persuaded [the preclusion analysis] could be done fairly in advance of the close of discovery," Status Conf. Tr. 13:25-14:2, it would only permit SPD to brief the FDCA preclusion issue once the record on the issue was fully developed. The parties agreed. Hence, because the record on this issue is now fully developed and because any issues of fact are to be tried before the Court rather than a jury, the Court will address the merits of SPD's motion, rather than treat it as a motion to dismiss under Rule 12(b)(6) or for summary judgment under Rule 56. *Accord Fournier*, 242 F. Supp. 2d at 335 (deciding, "for purposes of efficiency," to address a motion *in limine* on the merits rather than as a motion to dismiss or for summary judgment).

II. BACKGROUND

The Court assumes familiarity with its Opinion and Order dated June 3, 2014, *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, but the Court will briefly summarize portions of that decision that are relevant to the present motion.

C&D and SPD are competitors in the global market for home pregnancy test kits. Around August 2013, SPD began producing and marketing a new home pregnancy test kit called the "Clearblue Advanced Digital Pregnancy Test with Weeks Estimator" (the "Weeks Estimator"). The Weeks Estimator is designed to tell a woman if she is pregnant, but it has the added feature of also estimating the number of weeks that have passed since the woman last ovulated. As the Court earlier explained, "[t]he crux of C&D's claims is that the Weeks Estimator cannot be used to provide an estimate of how long a woman has been pregnant." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *4. This is because, "according to C&D, the medical profession does not measure pregnancy with reference to the time of ovulation—the time that an egg is released from the ovary—but rather measures it based on the 'universally accepted convention' that pregnancy begins at the time of the woman's last menstrual period." *Id.* (quoting Compl. ¶ 18). Based on this distinction, C&D alleges that SPD made a number of false statements in its advertising campaign for the Weeks Estimator, which included, *inter alia*, the Weeks Estimator's product packaging, the Weeks Estimator's television commercial, SPD's website, point-of-purchase displays, and an SPD press release.[1] In short, C&D contends that SPD's advertising for the Weeks Estimator—indeed, the very name of the product itself—conveys the message that the Weeks Estimator can tell a woman how many weeks she has been pregnant and that this message is false or misleading.

SPD moved to dismiss C&D's Complaint and opposed C&D's motion for a preliminary injunction primarily by asserting a preclusion defense. That is, SPD argued that the FDCA

[1] Following a separate motion *in limine*, the Court rejected SPD's request to limit the scope of the case to these specific pieces of advertising as opposed to the advertising claims (i.e., messages or assertions) contained in these pieces of advertising. *See Church & Dwight Co. v. SPD Swiss Precision Diagnostics GmbH*, No. 14-CV-585 (AJN), 2014 U.S. Dist. LEXIS 158551, at *10 (S.D.N.Y. Oct. 28, 2014) ("*Church & Dwight II*").

precludes C&D's Lanham Act claim because the FDA subjected the Weeks Estimator's labeling to a rigorous pre-approval process before the product was launched. In support of its FDCA preclusion argument, SPD submitted documentary evidence of its discussions with the FDA regarding the Weeks Estimator. The Court declined to take judicial notice of most of these documents with respect to the motion to dismiss, and, because the preliminary injunction was consolidated with an expedited bench trial on liability, the Court did not consider the documents in reaching its earlier decision.[2]

A. The Court's Motion to Dismiss Opinion

FDCA preclusion is premised on the FDA's "authority to regulate medical devices under the Medical Devices Amendments Act." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *8-9 (citing *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006)). That statute establishes three tiers, or classes, of devices, each subject to an increasingly stringent level of regulatory control to ensure safety and effectiveness. *Id.*; *see also* 21 U.S.C. § 360c(a). As a Class II device, the Weeks Estimator is subject to 21 U.S.C. § 360(k), more commonly known as the "510(k) process." *Id.* at *10 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-79 (1996)). The 510(k) process requires the party seeking to market the device to notify the FDA prior to marketing the device with "a description of the device and a statement of the intended use of the device, the proposed labeling to be included on the device, and the information necessary for the FDA to determine if the device is 'substantially equivalent' to a pre-existing device.'" *Id.* (citing 21 C.F.R. § 807.92 (2014); *Rita Med. Sys. v. Resect Med., Inc.*, No. C 05-03291 WHA, 2006 U.S. Dist. LEXIS 52366, at *7-9 (N.D. Cal. July 17, 2006)); *see also* 21 U.S.C. § 360c(i) (defining "substantial equivalence").

The Court's June 2014 Opinion noted that, because the FDCA "imposes a comprehensive set of requirements upon medical devices," and because the FDCA contains no private right of action, "courts have held that the FDCA may 'preclude' some claims that stray into the FDA's

[2] The Court instead limited its analysis to the allegations in C&D's Complaint, the Clearance Letter that the FDA issued to SPD for the Weeks Estimator which was attached to C&D's Complaint, and C&D's communications with the FDA. *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *14.

enforcement domain." *Id.* at *19 (citations and internal quotation marks omitted). "On the other hand, concerns about giving full effect to federal statutes—statutes such as the Lanham Act—that provide for a private right of action have made courts wary of applying this approach too broadly." *Id.* Combining these two lines of thinking and "[b]ased on the Court's survey of precedent," the Court concluded that "the basic application of the doctrine of FDCA preclusion is that courts refuse to usurp the FDA's role in the enforcement of the FDCA and the FDA's authority under that statute." *Id.* at *22. Synthesized further, "preclusion is required not only when a plaintiff 'seeks to enforce directly the FDCA through the Lanham Act' but also when a plaintiff attempts to 'maintain a Lanham Act claim [that] requires direct application or interpretation of the FDCA or FDA regulations.'" *Id.* (quoting *Healthpoint, Ltd. v. Stratus Pharms.*, 273 F. Supp. 2d 769, 786 (W.D. Tex. 2001)).

The Court's June 2014 Opinion held that C&D's Lanham Act claim implicates neither branch of FDCA preclusion. Rather, C&D's Lanham Act claim requires the Court to conduct a limited two-step inquiry: "determine the message conveyed to consumers by SPD's marketing and then determine whether that message is either literally false or likely to mislead and confuse consumers." *Id.* at *28 (citing *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010)). The FDCA did not preclude the Court from conducting this inquiry because, "[b]ased on the [motion to dismiss] record, it [did] not appear that either task requires the Court to interpret, apply, or enforce the FDCA, the FDA's regulations, or the Clearance Letter." *Id.* at *29. "For example," the Court continued,

> to decide that the Weeks Estimator was falsely advertised in violation of the Lanham Act as capable of measuring pregnancy based on the standard applied by healthcare professionals, the Court need not look to the FDA's regulations governing labeling medical devices with their intended uses. Nor need the Court make a determination whether the Weeks Estimator is in compliance with the FDA's regulations or restrictions imposed by the Clearance Letter. In this respect, C&D's claim is independent of the FDCA and FDA regulations and would exist even in their absence.

Id. at *29.

Lingering in the background of this discussion was the Ninth Circuit's decision in *POM Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012). That opinion had held, in essence, that Lanham Act claims might be precluded if the FDA had authorized the challenged name and label. The Court distinguished the Ninth Circuit's opinion from the facts available at the motion to dismiss stage by noting that the "regulatory scheme governing the Weeks Estimator does not—in itself—provide a basis to conclude that the Weeks Estimator box, label, or advertising has been authorized by the FDA." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *35-36. "In other words, while the Court in *Pom Wonderful* was able to find that the FDA had essentially blessed the name and label of the juice product at issue by promulgating regulations that plainly authorized the name and label, the [motion to dismiss record] demonstrate[d] merely a general prohibition against the misbranding of medical devices as to their intended uses." *Id.* at *36. Thus, because the Ninth Circuit's opinion suggested that FDA authorization might provide a basis for FDCA preclusion, and because the record was not developed enough to determine the extent to which the FDA had authorized the challenged labeling, the Court held that "it may be that SPD is able to re-raise this argument at a later stage, if appropriate given the development of the proceedings." *Id.* at *43. As noted, the Court later confirmed at a status conference with the parties, which was held after the Supreme Court reversed the Ninth Circuit's decision in *POM Wonderful*, that SPD would be permitted to re-raise the FDCA preclusion issue one final time following the close of discovery but prior to trial. *See* Status Conf. Tr. 9:1-10, 12:10-13:16, 14:3-7, 16:22-17:15.

B. FDA's Pre-Approval of the Weeks Estimator's Labeling

Consistent with this understanding, SPD submits the present motion *in limine* and attaches a number of exhibits documenting the FDA pre-approval process.[3] These exhibits reveal that, unlike the situation in *POM Wonderful* in which the challenged product labeling was merely consistent with existing FDA regulations, the Weeks Estimator's product packaging and

[3] In some instances, SPD did not actually attach the documents as an exhibit to the present motion, but instead referred the Court back to its earlier filings that the Court refused to consider in the context of the motion to dismiss.

at least one internet commercial (though not all of its advertising) were subject to extensive FDA pre-approval. SPD argues that the FDA's "involvement was so extensive as to constitute full control of the packaging even before its release." SPD Br. 17. C&D, in contrast, contends that the FDA merely "permitted" rather than "mandated" the Weeks Estimator's product packaging. C&D Br. 2. Based on the documentary support provided by both parties, a fairer characterization of the FDA's involvement lies somewhere in between these two poles.

In August 2012, for example, the FDA issued a "Hold Letter" with respect to SPD's 510(k) application because it had identified a concern with the Weeks Estimator: Women could misinterpret its results or use the product for unintended purposes, with potentially adverse health consequences. Specifically, the Hold Letter expresses the concern that the product's

> weeks indicator feature may provide misleading information to lay population of users and the Indications for Use and labeling of this device is currently inadequate to assure that the intended user (untrained lay users at home) will understand the output of this new feature and be able to interpret it safely. For example, the output of this test is not aligned with gestational aging done by healthcare professionals (i.e., it will under-estimate gestational age by an average of 2 weeks). . . . Provided you are able to adequately respond to all items in this hold letter and adequately address all review questions pertaining to this submission, we are considering a [substantial equivalence] with limitations decision for clearance of this submission. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Indications for Use and in your device's labeling if your device is cleared.

Gittins Decl. Ex. A. at 2 ("Hold Letter"). The Hold Letter then provides specific changes to the Weeks Estimator's Indications for Use and labeling. For example, the Hold Letter requests changing the Weeks Estimator's Indications for Use to state, *inter alia*:

> This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that can not be substituted for a doctor's determination of gestational age.

Hold Letter 2. With respect to the product's labeling, the Hold Letter requests, among other things, that SPD remove the following statement from every area of the box: "*Also Tells You How Far Along You Are.*" Hold Letter 3. The Hold Letter also requests changing the name of

the product to the "Weeks Estimation Indicator" rather than "Conception Indicator," which was SPD's initial name for the product. Hold Letter 3. SPD pushed back and proposed "Weeks Estimator," which the FDA accepted, Hold Letter 3, but there is no indication that SPD proposed other alternatives to the product's name or that the FDA would have rejected something other than "Weeks Estimator." In subsequent communications with SPD concerning the Weeks Estimator's labeling, the FDA opined on other aspects of the product's packaging, including font size and the location of certain language on the box. *See* Gittins Decl. ¶ 30 & Ex. D.

As the Hold Letter indicates, the FDA requested these changes under Section 513(i)(1)(E) of the FDCA, which provides that "when determining that a device can be found substantially equivalent to a legally marketed device, the [FDA] may require a statement in labeling[4] that provides appropriate information regarding a use of the device not identified in the proposed labeling." 21 U.S.C. § 360c(i)(1)(E)(i). The resulting clearance from the FDA is known as "SE [substantial equivalence] with limitations." Gittins Decl. ¶¶ 23-26 & Ex. B. A finding of substantial equivalence means the device "has the same technological characteristics as the predicate device" or "has different technological characteristics and . . . is as safe and effective as a legally marketed device, and . . . does not raise different questions of safety and effectiveness than the predicate device." § 360c(i)(1)(E)(ii)(III); *see also* § 360c(i)(1)(A).

On December 10, 2012, the FDA issued its Clearance Letter, which allowed SPD to begin marketing the Weeks Estimator. Compl. Ex. A. ("Clearance Letter"). The Clearance Letter is largely consistent with the restrictions noted in the Hold Letter, but it also notes, for example, that "Performance of the Weeks Estimator should not be displayed on your box labeling. Box labeling should instruct users to see the package insert for test instructions and for more information on the Weeks Estimator." Clearance Letter 1. The Clearance Letter further states that "a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling." Clearance Letter 3. Finally, the Clearance Letter also states that

[4] "Labeling" is defined elsewhere as "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

"FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." Clearance Letter 3.

In October and November 2013, C&D wrote to the FDA asking it to take "corrective action" against SPD for alleged violations of the Clearance Letter's labeling restrictions. Knowles Decl. Ex. A, B. Those letters raise contentions that overlap with C&D's assertions in this action. The FDA then reached out to SPD regarding some of these issues, which led SPD to submit a "mitigation proposal" to make certain changes to its product labeling and nationally aired television commercial. Gittins Decl. ¶ 56 & Ex. Q; Vinti Decl. Ex. 11. The FDA's response to SPD's mitigation proposal again reveals the FDA accepting some but not all of SPD's suggestions. Vinti Decl. Ex. 11. For example, the FDA ordered SPD to cease airing the Weeks Estimator's nationally televised commercial by December 6, 2013 because the commercial "still does not convey the limitations of your Week[s] Estimator completely, nor does it clearly state that the device can only estimate weeks since ovulation (and not weeks of pregnancy) and therefore does not present a balanced and accurate description of your device to consumers." Vinti Decl. Ex. 11. The FDA subsequently approved a modified commercial for internet use only, which, *inter alia*, "display[s] the [Indications for Use] statement in its entirety, in text and against a blank screen with sufficient time to allow the statement to be read by the viewer." Gittins Decl. ¶¶ 65-66 & Exs. V-W.

III. DISCUSSION

There is no doubt that the FDA subjected the Weeks Estimator's labeling to an extensive pre-approval process. The only question that remains is whether such extensive pre-approval precludes C&D's Lanham Act claims. The Court concludes it does not. In reaching this conclusion, the Court first explains below why *POM Wonderful*'s reasoning applies with equal force to medical device labeling and why FDA pre-approval does not bar Lanham Act claims, a conclusion that is bolstered by related Supreme Court precedent from the field of pre-emption. The Court then briefly discusses the two post-*POM Wonderful* cases that are on point, neither of

which alters this Court's conclusion. Finally, the Court examines SPD's argument that C&D's Lanham Act claim still requires the Court to interpret, apply, or enforce the FDCA, a field of FDCA preclusion that *POM Wonderful* appears to have left untouched.

A. *POM Wonderful*'s Reasoning Applies with Equal Force Here

As a preliminary matter, the Court notes that although *POM Wonderful* involved food and beverage labeling, its reasoning applies with equal force to medical device labeling. To explain, foods, drugs, and cosmetics regulated by the FDA are subject to various levels of oversight depending on the nature of the product, as suggested by the three classes of regulatory oversight of medical devices discussed above. The product at issue in *POM Wonderful*, fruit juice, receives less oversight than certain medical devices and prescription drugs. *POM Wonderful*, 134 S. Ct. at 2235. Nonetheless, in *POM Wonderful*, Coca-Cola contended that the FDA promulgates very specific regulations governing the naming and labeling of fruit juices, and, because Coca-Cola must comply with those regulations, it argued that Lanham Act claims that challenge the naming or labeling of fruit juice must be precluded. The Supreme Court disagreed, of course, but indicated in its opinion that the issue before it pertained to food and beverage labeling. For example, the opinion's introductory summation states that "[t]here is no statutory text or established interpretive principle to support the contention that the FDCA precludes Lanham Act suits *like the one brought by POM in this case*. . . . Competitors, in their own interest, may bring Lanham Act claims like POM's *that challenge food and beverage labels* that are regulated by the FDCA." *Id.* at 2233 (emphasis added).

Nevertheless, the Supreme Court's reasoning was not limited to a specific area of the FDCA. Instead, much of the Supreme Court's analysis applies with equal force to the rest of the FDCA, including regulation of medical device labeling. To begin with, the Supreme Court's analysis focused on the two statutes as a whole, emphasizing that they serve different, but complementary, purposes. "The Lanham Act creates a cause of action for unfair competition through misleading advertising or labeling. Though in the end consumers also benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers." *Id.* at 2234.

"The FDCA statutory regime," in contrast, "is designed primarily to protect the health and safety of the public at large." *Id.* In addition, the Lanham Act "relies in substantial part for its enforcement on private suits brought by injured competitors," while "[p]rivate parties may not bring enforcement suits" under the FDCA. *Id.* at 2235.

Despite these divergent purposes and enforcement mechanisms, the statutes occasionally overlap. For example, "[t]he FDCA prohibits the misbranding of food and drink," and "[a] food or drink is deemed misbranded if, *inter alia*, 'its labeling is false or misleading.'" *Id.* at 2234 (citing 21 U.S.C. § 343(a)). Recognizing this overlap, the Supreme Court turned to principles of statutory construction, but it declined to decide which of POM's and Coca-Cola's preferred maxims of construction to apply. *Id.* at 2237. Instead, it stated that "[e]ven assuming that Coca-Cola is correct that the Court's task is to reconcile or harmonize the statutes and not, as POM urges, to enforce both statutes in full unless there is a genuinely irreconcilable conflict, Coca-Cola is incorrect that the best way to harmonize the statutes is to bar POM's Lanham Act claim." *Id.* Harmonizing the statutes did not require barring Lanham Act claims for the simple reason that the statutes do not actually conflict with one another.

Most importantly, neither statute contains an express prohibition or limitation on enforcement of the other, which was "of special significance because the Lanham Act and the FDCA have coexisted since the passage of the Lanham Act in 1946." *Id.* "If Congress had concluded, in light of experience, that Lanham Act suits could interfere with the FDCA, it might well have enacted a provision addressing the issue during these 70 years." *Id.* Such long co-existence was of even greater import to the Supreme Court in light of the fact that Congress enacted amendments to both statutes during this time, "including an amendment that added to the FDCA an express pre-emption provision with respect to state laws addressing food and beverage misbranding." *Id.* The Supreme Court found it "significant that the complex pre-emption provision distinguishes among different FDCA requirements." *Id.* at 2238. "By taking care to mandate express pre-emption of some state laws, Congress if anything indicated it did not intend

the FDCA to preclude requirements arising from other sources." *Id.* (citing *Setser v. United States*, 566 U.S. __, __, 132 S. Ct. 1463, 182 L. Ed. 2d 455, 461-62 (2012)).

In short, the Supreme Court concluded, "[t]he Lanham Act and the FDCA complement each other in major respects, for each has its own scope and purpose. Although both statutes touch on food and beverage labeling, the Lanham Act protects commercial interests against unfair competition, while the FDCA protects public health and safety." *Id.* In addition, the respective remedies of the two statutes promote a more "fundamental" harmony:

> Enforcement of the FDCA and the detailed prescriptions of its implementing regulations is largely committed to the FDA. The FDA, however, does not have the same perspective or expertise in assessing market dynamics that day-to-day competitors possess. Competitors who manufacture or distribute products have detailed knowledge regarding how consumers rely upon certain sales and marketing strategies. Their awareness of unfair competition practices may be far more immediate and accurate than that of agency rulemakers and regulators. Lanham Act suits draw upon this market expertise by empowering private parties to sue competitors to protect their interests on a case-by-case basis. By serv[ing] a distinct compensatory function that may motivate injured persons to come forward, Lanham Act suits, to the extent they touch on the same subject matters as the FDCA, provide incentives for manufacturers to behave well. Allowing Lanham Act suits takes advantage of synergies among multiple methods of regulation.

Id. at 2238-39 (citations and internal quotation marks omitted).

These conclusions all apply with equal force to Lanham Act claims relating to medical devices. For example, the FDCA's regulation of medical devices, though not of the same vintage as other parts of the FDCA, has nonetheless co-existed with the Lanham Act for nearly 40 years. *See* Medical Device Amendments Act of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976). Moreover, Congress amended the FDCA to include a pre-emption provision for medical devices that is substantially similar to the pre-emption provision for food labeling discussed in *POM Wonderful*. *Compare* 21 U.S.C. § 343-1 *with* 21 U.S.C. § 360k. Thus, as with the regulation of food and beverage labeling at issue in *POM Wonderful*, during nearly forty years of co-existence, Congress has chosen to pre-empt certain state laws concerning medical devices, while saying nothing about preclusion of federal statutes such as the Lanham Act. Finally, the

FDA's perspective and expertise as compared to the knowledge of day-to-day competitors is at least as limited with respect to medical devices as it is for food and beverage labeling. Thus, be it food or medical devices, "[a]llowing Lanham Act suits takes advantage of synergies among multiple methods of regulation." *POM Wonderful*, 134 S. Ct. at 2238.

B. FDA Pre-Approval Does Not Bar Lanham Act Claims

On the whole, then, the Supreme Court reasoned that the Lanham Act and FDCA complement each other, and, as demonstrated above, this harmony does not depend on which aspect of the FDCA is at issue. SPD argues, however, that the Supreme Court's opinion carved out Lanham Act claims that challenge labeling the FDA has pre-approved because the opinion noted that "[u]nlike other types of labels regulated by the FDA, such as drug labels, *see* 21 U.S.C. § 355(d), it would appear the FDA does not preapprove food and beverage labels under its regulations and instead relies on enforcement actions, warning letters, and other measures." *Id.* at 2239. SPD's argument would be more persuasive but for the Supreme Court's rejection of almost identical arguments in two separate cases.

First, the Supreme Court rejected the pre-approval argument in *POM Wonderful* itself. As amicus curiae, the Government argued "that a Lanham Act claim is precluded 'to the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of [the] label.'" *Id.* at 2240 (quoting Br. for United States as *Amicus Curiae* 11). The Supreme Court countered that "[i]n addition to raising practical concerns about drawing a distinction between regulations that 'specifically . . . authorize' a course of conduct and those that merely tolerate that course, the flaw in the Government's intermediate position is the same as that in Coca-Cola's theory of the case." *Id.* The Government's and Coca-Cola's arguments were flawed because they "assume[] that the FDCA and its regulations are at least in some circumstances a ceiling on the regulation of food and beverage labeling. But, as discussed above, Congress intended the Lanham Act and the FDCA to complement each other with respect to food and beverage labeling." *Id.* Thus, because the FDCA does not act as a ceiling on the regulation of food and beverage labeling, FDA pre-approval is beside the point.

Second, the Supreme Court rejected an almost identical pre-approval argument in *Wyeth v. Levine*, 555 U.S. 555 (2009), which, although a pre-emption rather than a preclusion case, is on all fours with the facts here. Despite the difference in doctrines, "pre-emption . . . principles are instructive insofar as they are designed to assess the interaction of laws that bear on the same subject." *Pom Wonderful*, 134 S. Ct. at 2236.

In *Wyeth*, a drug manufacturer similarly argued "that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue." *Wyeth*, 555 U.S. at 573-74. Applying an analysis that is parallel to its reasoning in *POM Wonderful*, the Supreme Court disagreed. For example, the Supreme Court noted that Congress may "have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* at 574. It further commented that "when Congress enacted an express pre-emption provision for medical devices in 1976, it declined to enact such a provision for prescription drugs." *Id.* at 567 (citations omitted). As in *POM Wonderful*, Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. The Supreme Court in *Wyeth* also emphasized that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs . . . . State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." *Wyeth*, 555 U.S. at 578-79 (footnote omitted). This observation echoes the observation in *POM Wonderful* that the Lanham Act leverages the knowledge and financial incentives of market competitors to augment the FDA's limited resources and narrower perspective in the regulation of false and misleading food and beverage labels. *POM Wonderful*, 134 S. Ct. at 2238. Since the FDA's pre-approval of medical device

packaging is at least as rigorous as its pre-approval of drug labeling, *Wyeth*'s pre-emption analysis informs this Court's approach to FDCA preclusion of the Lanham Act.

Despite this consistent rejection of the pre-approval argument, SPD attempts to distinguish the present facts from those in *POM Wonderful*, which did not involve FDA pre-approval of any specific labeling, by noting that the FDA specifically approved *this* product's labeling. Although this fact is a point of distinction, it does not alter the flaw in the pre-approval argument, which is an assumption that the FDCA and its regulations are a ceiling on the regulation of medical device labeling. SPD also seeks to distinguish *POM Wonderful* by arguing that whether or not the FDCA acts as a ceiling on the regulation of medical device labeling, the FDA's Hold and Clearance Letters made clear that the FDA intended *its* approval of SPD's product packaging to be the final word on the issue. This argument similarly misses a key lesson from both *POM Wonderful* and *Wyeth*: It is for Congress, not the FDA, to determine whether the FDCA and its regulations are a ceiling on the regulation of medical devices. *See POM Wonderful*, 134 S. Ct. at 2241 ("An agency may not reorder federal statutory rights without congressional authorization."). Regardless, it is doubtful that the FDA would agree with the position that SPD ascribes to it. Notably, the FDA's Clearance Letter expressly advises SPD "that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." Clearance Letter 3. Nor is there any other indication in the FDA's correspondence that it intended its actions to preclude Lanham Act claims.

Finally, under a theory similar to the floor-and-ceiling argument, SPD contends that C&D's Lanham Act claim should be barred under *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), which held that an "action was barred because it directly conflicted with the agency's policy choice to encourage flexibility to foster innovation." *POM Wonderful*, 134 S. Ct. at 2241. But, as in *POM Wonderful*, SPD can point to no FDA actions "discuss[ing] or even cit[ing] the Lanham Act, and [SPD] cites no other statement in the [FDA's communications]

suggesting that the FDA considered the full scope of the interests the Lanham Act protects." *Id.* In short, "[t]his is not a case where a lawsuit is undermining an agency judgment, and in any event the FDA does not have authority to enforce the Lanham Act." *Id.*

In sum, the Court concludes that the FDA's pre-approval of the Weeks Estimator's labeling does not preclude C&D from bringing a Lanham Act claim for false advertising. Applying *POM Wonderful*, the Court will not "elevate the FDCA and the FDA's regulations over the private cause of action authorized by the Lanham Act" because "the FDCA and the Lanham Act complement each other in the federal regulation of misleading labels." *Id.* at 2241.

C. Other Cases Interpreting *POM Wonderful*

As far as the Court is aware, only two opinions decided post-*POM Wonderful* are relevant to the question at hand—one is consistent with this Court's conclusion, while the other implicitly adopts SPD's argument, but without fully engaging the issue.

The first case, *Catheter Connections, Inc. v. Ivera Medical Corp.*, No. 2:14-CV-70-TC, 2014 U.S. Dist. LEXIS 98206 (D. Utah July 17, 2014), also addressed FDCA preclusion of Lanham Act claims involving medical devices. Like SPD, the defendants in that action argued that the plaintiff's "claims under the Lanham Act . . . are barred because medical device testing and regulatory approval are exclusively handled by the FDA under the FDCA." *Id.* at *7. The *Catheter Connections* court agreed that "[i]f the circumstances 'inherently require' court interpretation of the FDCA and implementing regulations, the area of inquiry is precluded." *Id.* at *13 (quoting *Cottrell, Ltd. v. Biotrol Int'l Inc.*, 191 F.3d 1248, 1256 (10th Cir. 1999)). But, under this reasoning, the court found that the only precluded claim was an assertion that the defendant "has not complied with FDCA Section 510(k)," *id.* at *16, which would require the court to decide in the first instance whether Section 510(k) clearance is required—a determination left exclusively to the FDA. The remainder of the false advertising claims were not barred because, "[f]or each of those, a determination of the issues raised by Catheter Connections would not require FDA expertise and would not require the court to interpret the FDCA or FDA regulations." *Id.* at *17-18. Instead, those claims focused on the "substance of

[defendant's] representations in the context of the medical device market and what drives buyers' purchasing decisions." *Id.* at *19. *Catheter Connections* is thus consistent with the Court's earlier Opinion at the motion to dismiss stage and its holding here.

The second case is *JHP Pharmaceuticals, LLC v. Hospira, Inc.*, No. CV 13-07460 DDP (JEMx), 2014 U.S. Dist. LEXIS 142797 (C.D. Cal. Oct. 7, 2014). On the one hand, that case similarly observed that "[t]he logical building blocks of [*POM Wonderful*'s] specific holding with regard to food and beverage labeling would seem to be equally applicable to food and beverage advertising, drug marketing, medical device labeling, cosmetic branding, or any other kind of marking or representation which would fall under both the Lanham Act and the FDCA, *unless* preclusion is required for some specific reason." *JHP Pharmaceuticals, LLC*, 2014 U.S. Dist. LEXIS 142797, at *13. But in a footnote, the court briefly commented that

> the Supreme Court suggested two such reasons in *Pom Wonderful*: the FDA may have pre-approved a particular labeling scheme, as in the labeling of FDA-approved drugs; or the agency may have authorized a menu of possible lawful choices for manufacturers, as was the case in *Geier*. (The common element, of course, is positive regulatory action in the matter by the FDA.).

Id. at *13 n.5. As extensively discussed above, the Court disagrees with the first half of this conclusion based on the Supreme Court's refusal to accept the Government's pre-approval argument in *POM Wonderful* and its refusal to pre-empt state tort claims in the face of a pre-approved drug label in *Wyeth*, neither of which are discussed in *JHP Pharmaceuticals*.[5]

D. C&D's Claim Does Not Seek to Enforce the FDCA

Although the Court is convinced that Lanham Act claims are not precluded merely because the FDA pre-approved a medical device's labeling, the Court agrees with the *Catheter Connections* court that *POM Wonderful* did not disturb the longstanding proposition that private parties may not use the Lanham Act as a vehicle to enforce the FDCA. That is, because the FDCA does not contain a private right of action, claims that require a court to interpret, apply, or enforce the FDCA remain precluded. *See Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at

[5] The analysis of *POM Wonderful* in *JHP Pharmaceuticals* is further discounted because the plaintiff's claim in that case failed for an alternative reason, so the court did not resolve this "thorny" issue. *Id.* at *28-29.

*21-22. But it is still the case that C&D's claims will only require the Court to "determine the message conveyed to consumers by SPD's marketing and then determine whether that message is either literally false or likely to mislead and confuse consumers." *Id.* at *28. Even in light of the more fully developed record, which reveals the extent of the FDA's pre-approval of the Week's Estimator's labeling, neither task "requires the Court to interpret, apply, or enforce the FDCA, the FDA's regulations, or the Clearance Letter." *Id.* at *29.[6]

Attempting to shoehorn C&D's claim into the category of precluded claims that usurp the FDA's role, SPD argues that C&D is challenging not just the Weeks Estimator's advertising, but the FDA's clearance of the product itself. For example, SPD argues that "C&D is attacking the Product itself as inherently misleading and unsafe. In other words, C&D is asking this Court to reverse the FDA clearance because, according to C&D, the Product is providing inherently misleading information to consumers." SPD Br. at 1. But C&D has made clear in its Complaint and throughout this litigation that it is challenging advertising that literally or implicitly conveys the message that the product does something it cannot—estimate the number of weeks a woman has been pregnant based on what C&D contends is universally accepted medical practice. "C&D does not seek to overturn [the] FDA's clearance of the Product for the intended use of (i) detecting whether or not a woman is pregnant and (ii) estimating how many weeks [have passed] since she last ovulated." C&D Br. at 1. Relatedly, SPD argues that C&D's challenge to the name of the product itself is a "direct assault" on the FDA's clearance of the product. But challenging the product's name is not the same as challenging the FDA's clearance of the product for its intended use. Moreover, although the FDA accepted the name "Weeks Estimator," the FDA did not indicate that SPD is prohibited from considering alternatives to the "Weeks Estimator," other than, perhaps, the already rejected name ("Conception Indicator").

[6] Portions of C&D's Complaint suggest that it might be attempting to enforce the FDCA, but C&D earlier clarified that this was not its intention and that "its references to the FDA's determination that the Weeks Estimator does not measure the duration of pregnancy based on time of last menstruation is evidence that SPD's marketing of the product for this use is false, but C&D's claim would exist even in the absence of the FDA's determination." *Church & Dwight I*, 2014 U.S. Dist. LEXIS 76752, at *28.

A more valid concern is that SPD might find itself stuck between a rock and a hard place, trying to honor the FDA's wishes while avoiding Lanham Act liability. The Court believes that this concern is lessened here for the same reason it was mitigated in *Wyeth*: A mere finding that a medical device is falsely advertised does not necessarily proscribe use of a device that the FDA has pre-approved or labeling that the FDA has required. In *Wyeth*, for example, the defendant drug manufacturer argued that a state jury's finding that its drug label failed to adequately warn of the dangers of a particular use of its drug (IV-push administration) was the equivalent of a proscription of that use, which the FDA had approved. *Wyeth*, 555 U.S. at 565. In response, the Supreme Court cited approvingly the Vermont Supreme Court's explanation that

> the jury verdict established only that Phenergan's warning was insufficient. It did not mandate a particular replacement warning, nor did it require contraindicating IV-push administration: "There may have been any number of ways for [Wyeth] to strengthen the Phenergan warning without completely eliminating IV-push administration."

Id. (quoting *Levine v. Wyeth*, 183 Vt. 76, 93 n.2 (2006)). Similarly, a finding that a medical device is falsely advertised will not itself prohibit the use of a medical device that the FDA has approved or mandate any particular replacement labeling different from what the FDA has already approved as there may be any number of ways to advertise the product that do not mislead consumers and comply with FDA requirements. Indeed, *Wyeth* suggests an iterative process in which the manufacturer, which at all times "remains responsible for updating [its] labels," *id.* at 568, would "change its drug label based on safety information that becomes available after a drug's initial approval" with FDA input and approval if required, *id.* at 567. *See also id.* at 571 ("Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications."). The FDA's Clearance Letter similarly suggests that SPD may want or need to make changes to the Weeks Estimator's labeling, which would require FDA approval. Clearance Letter 3 ("[A] new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.").

"[A]bsent clear evidence that the FDA would not have approved a change to Phenergan's label, [the Supreme Court would] not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Wyeth*, 555 U.S. at 571. Similarly, absent clear evidence that the FDA would not approve a change to the Weeks Estimator's labeling in response to concerns that it is misleading consumers, there is no reason to conclude that it would be impossible for SPD to comply with both the FDCA and the Lanham Act.[7]

IV. CONCLUSION

Therefore, because the FDCA and Lanham Act complement each other, and because FDA pre-approval of the Weeks Estimator's labeling does not preclude C&D from bringing a Lanham Act claim, SPD's motion *in limine* is DENIED. This resolves ECF No. 223.

SO ORDERED.

Dated: March 24, 2015
New York, New York

ALISON J. NATHAN
United States District Judge

[7] SPD makes much of the fact that the FDA requested SPD to make some changes to the product's packaging following C&D's complaints to the FDA in 2013. But there is still no reason to assume that, in the event SPD is found liable for false advertising under the Lanham Act, the FDA would prohibit SPD from making changes to its product packaging that would enable it to comply with both the Lanham Act and the FDCA.